

Application No. 10/613,115  
Reply to Office Action mailed April 7, 2005

Attorney Docket: S-9-6

### REMARKS

#### Re. The Office Action

Claims 1-32, 58, and 59 were pending in the Application. Claim 1 and its dependent claims are amended as discussed below, and Claim 60 is new, based on language previously set forth in Claim 1. Thus, Claims 1-32, and 58-60 are now pending.

By the Office Action, Claims 1-32, 58 and 59 are rejected under the second paragraph of 35 U.S.C. 112 as being indefinite and unclear; Claims 1, 3-4, 14, 18, and 20-21 are rejected under 35 U.S.C. 102 (e) as being anticipated by U.S. Patent No. 5,433,739 ("Sluijiter"); Claims 1, 3-4, 10-11, 14, 18, 20-21, and 58 are rejected under 35 U.S.C. 102 (e) as being anticipated by U.S. Patent No. 6,007,570 ("Sharkey"); Claims 2, 28-29, and 31-32 are rejected under 35 U.S.C. § 103 (a), over U.S. Patent No. 5,433,739 (Sluijiter); Claims 2, 9, 28-29, and 31-32 are rejected under 35 U.S.C. § 103 (a), over U.S. Patent No. 6,007,570 ("Sharkey"); and Claims 1-32, 58-59 are rejected under the judicially created doctrine of obviousness type double patenting over Claims 1-56 of U.S. Patent No. 6,602,248. The Office Action also cited two typographical errors in the first paragraph of the Specification for correction.

On the basis of the present amendments and for the reasons herein, reconsideration and allowance of the Application is respectfully requested.

#### Re. Corrections to the Specification

Typographical errors on the first paragraph of page 1 of the Specification are corrected, and the status of cross-referenced applications in the Specification is updated. Accordingly, withdrawal of the objection to the Specification is respectfully requested.

#### Re. Rejection of Claims 1-32 and 58-59 under 35 U.S.C. 112, second paragraph

Claims 1-32 and 58-59 are rejected under 35 U.S.C. 112, second paragraph on the basis that it was not clear what result is effected.

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Claim 1 is herewith amended to specify that the method includes contacting the disc with a heat delivery element, sufficient to decompress said disc such that pressure on a nerve root is reduced as described, for example at page 5, lines 24-27 in the Specification wherein the effect of the method is stated, and at page 6, lines 19-22 wherein it is disclosed that the high frequency voltage applied, effects a controlled depth of thermal heating to reduce pressure on the annulus fibrosis. Accordingly, withdrawal of this basis for rejecting the claims is respectfully requested.

Re. Rejection of Claims 1, 3-4, 14, 18, and 20-21 under 35 U.S.C. 102 (e) in view Sluijter

Claims 1, 3-4, 14, 18, and 20-21 are rejected under 35 U.S.C. 102 on the basis that Sluijter anticipates the claims because Sluijter places an electrode in the nucleus and, by applying Rf energy, heats the disc to effect changes in the nucleus. See the Office Action.

For the following reasons the Applicants disagree with the rejection and, in view of the present amendments, respectfully request withdrawal of the rejection.

As described in the Abstract and the Specification, e.g., at Col. 2, lines 56-60, Sluijter is concerned with a method of relieving back pain that involves destroying nerves that innervate the disc. Sluijter does this by positioning an electrode remote from the nerves to be destroyed; and heating an intermediate structure, which then carries over to more remote neural structures, thereby destroying those remote neural structures. See Col. 2, lines 26-32.

The Applicant's method, on the contrary does not destroy neural structures but, as is set forth in Claim 1 and as described in the specification, involves decompressing the disc by contacting at least a first region of a nucleus pulposus of the inter-vertebral disc with at least one heat delivery element of an electrosurgical system, and applying a first high frequency voltage to the heat delivery element sufficient to decompress the disc such that pressure on a nerve root is reduced.

Thus Sluijter does not anticipate Claim 1 because Sluijter does not teach the method of Claim 1 since Claim 1 does not destroy nerves remotely, but on the contrary Claim 1 decompresses the disc such that pressure on the nerve root is reduced, as described for example in the Specification at page 5, lines 24-27.

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Accordingly, since Claims 3-4, 14, 18, and 20-21 depend from Claim 1, they all include the limitations of Claim 1, and therefore all claims are patentable over Sluijiter. Accordingly, withdrawal of this basis for rejecting the claims is respectfully requested.

Re. Rejection of Claims 1, 3-4, 10-11, 14, 18, 20-21, and 58 under 35 U.S.C. 102 (e) in view  
Sharkey

Claims 1, 3-4, 10-11, 14, 18, 20-21, and 58 are rejected under 35 U.S.C. 102 (e) as being anticipated by Sharkey on the basis that Sharkey places an electrode in the nucleus and, by applying Rf energy and heat, changes in the nucleus. See the Office Action.

For the following reasons the Applicants disagree with the rejection and, in view of the present amendments, respectfully request withdrawal of this basis for rejecting the claims.

As noted above, Claim 1 involves a method comprising contacting at least a first region of a nucleus pulposus of the inter-vertebral disc with at least one heat delivery element of an electrosurgical system; and applying high frequency voltage to the delivery element, sufficient to decompress the disc such that pressure on a nerve root is reduced.

In contrast to Claim 1, Sharkey, as described for example in its Abstract, is concerned with a method and apparatus of repairing fissure in the annulus pulposus, comprising placing an energy source adjacent to the fissure, and providing energy for a sufficient time to cause the collagen to weld. Although Sharkey's procedure is concerned with a procedure on the disc, in Sharkey there is no suggestion or teaching of a method or effect resulting from applying high frequency voltage to a heat delivery element sufficient to decompress the disc such that pressure on nerve roots is reduced.

Thus Sharkey does not anticipate Claim 1 and, therefore, since dependent Claims 3-4, 10-11, 14, 18, 20-21, and 58 include all the limitations of Claim 1, all claims are patentable over Sharkey. Accordingly, withdrawal of this basis for rejecting the claims is respectfully requested.

Re. Rejection of Claims 2, 28-29, and 31-32 under 35 U.S.C. 103 (a) in view  
Sluijiter

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Claims 2, 28-29, and 31-32 are rejected under 35 U.S.C. 103 (a) in view Sluijiter on the basis that it would have been obvious to move the probe to various locations within the disc to ensure sufficient heating to effect the intended result, as well as to select particular dimensions. See the Office Action.

For the following reasons the Applicants disagree with the rejection and, in view of the present amendments, respectfully request withdrawal of this basis for rejecting the claims.

As noted above, Sluijiter does not teach or suggest applying a high frequency voltage to an energy delivery element sufficient to decompress the disc such that pressure on nerve roots is reduced to relieve pain, as set forth in Claim 1. Accordingly, in view of this failure by Sluijiter, therefore Claim 1 and its dependent Claims 2, 28-29, and 31-32 are not rendered unpatentable under 35 U.S.C. 103 (a), and thus withdrawal of this rejection is respectfully requested.

Re. The rejection of Claims 2, 9, 28-29, and 31-32 under 35 U.S.C. 103 (a) in view Sharkey

Claims 2, 9, 28-29, and 31-32 are rejected under 35 U.S.C. 103 (a) as being obvious in view Sharkey on the basis that the movement of the probe within the disc would have been obvious to insure sufficient heating to effect the intended result.

As noted above, in Sharkey there is no suggestion or teaching of a method or effect resulting from applying high frequency voltage to the delivery element sufficient to decompress nerve roots to relieve pain as set forth in Claim 1. Accordingly, in view of this failure by Sharkey, Claim 1 and its dependent Claims 2, 28-29, and 31-32 are not rendered unpatentable under 35 U.S.C. 103 (a), and therefore withdrawal of this rejection is respectfully requested.

Re. The rejection of Claims 1-32, and 58-59 under the doctrine of obviousness double patenting

The Applicants will file a timely terminal disclaimer if upon reconsideration of the claims as amended, this ground remains the only basis for rejecting the claims.

CONCLUSION

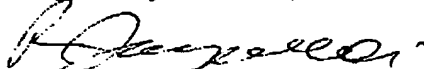
All claims in the Application are patentable over the cited references, and are in condition for allowance. Accordingly, reconsideration and allowance of the Application is respectfully

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requested. If an issue remains that can be resolved by telephone, kindly contact the undersigned at (408) 735-6486.

Respectfully submitted,



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